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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,802	02/19/2002	Dennis R. Burton	07300-025002	7485

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EXAMINER

WORTMAN, DONNA C

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/079,802	BURTON ET AL.
	Examiner Donna C. Wortman, Ph.D.	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 2/19/02, 3/26/02.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 15-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 15-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> .	6) <input type="checkbox"/> Other: _____.

Claims 15 and 16 were amended and claims 17-23 were added by preliminary amendment. Claims 15-23 are pending and under examination.

Claim 15 is objected to because of the following informalities: In line 1, "A antibody ..." should read "An antibody ...". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that *E. coli* ATCC 69522 is required in order to practice the invention of claim 16, since *E. coli* ATCC 69522 is recited in the claim and since the specificity of the antibody of claim 16 is only defined in terms of the specificity of *E. coli* ATCC 69522. Applicant must comply with the biological deposit requirements, 37 CFR 1.801-1.809, for *E. coli* ATCC 69522 in this application. Please see MPEP 2402-2410.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it is drawn to "A(n) antibody ... obtained by the method comprising ..." but does not recite language that would serve to relate the (second) antibody obtained in step d) with the preamble of the claim. If the second antibody of step d) is intended to be the antibody to which claim 15 is drawn, it is suggested that the claim language might be clarified by amending the claim to add "wherein the second antibody is an antibody that binds to a previously unknown epitope."

Claims 16-23 are indefinite because each is drawn to "The antibody of claim ..." without clear antecedent, since each claim depends directly or ultimately from claim 15 which recites the term "antibody" several times: "A(n) antibody"; "a first antibody"; and "the second antibody." Clarification is needed.

Claims 15-23 are confusing because each is drawn to an antibody that binds to a previously unknown epitope, which antibody is selected by binding an antigen to a preselected first antibody that is bound to a solid support, contacting the antibody-bound antigen to a combinatorial library of antibodies, and selecting and obtaining a second antibody from the combinatorial library, where the second antibody is bound to a previously unknown epitope. Example 5, beginning on page 61 of the specification, discloses use of monoclonal antibody Mab 1103, a preselected first antibody to herpes simplex glycoprotein D, in the claimed method. The last sentence of Example 5 and of the specification states: "Some of the clones were identified as AC8 (ATCC 69522) as previously identified neutralizing antibody specific for glycoprotein gD (Burioni, et al., *supra*)." Since clones identified by the claimed method apparently bound to a

previously identified epitope, and were in fact the same clones as identified by a slightly different method, it is not clear what is meant by "an antibody that binds to a previously unknown epitope" in the context of claims 15-23, and particularly of claim 16, which recites "wherein the antibody has the specificity of an antibody produced by *E. coli* ATCC 69522."

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-20, 22 and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7 and 8 of U.S. Patent No. 6,156,313. Although the conflicting claims are not identical, they are not patentably distinct from each other because, insofar as claims 15-20, 22 and 23 read on Fab8, produced by the plasmid deposited by ATCC 69522 or antibodies having the same specificity as those claimed in claims 1-5, 7 and 8 of the patent, they are deemed to be the same as or obvious over the antibodies claimed in the patent, regardless of the method by which the antibody was selected or identified.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-20, 22 and 23 rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burioni et al (Proc. Natl. Acad. Sci. 91:355-359, 1994), cited on PTO 892, attached. Insofar as claims 15-20, 22 and 23 read on Fab8 or antibodies having the same specificity as Fab8 as disclosed in Burioni et al., they are deemed to be anticipated by or obvious over Burioni et al., regardless of the method by which the antibody was selected or identified.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
December 12, 2002